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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,635	07/31/2001	Garry P. Nolan	A-64260-41RMS/AMS	6702

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EXAMINER

WESSENDORF, TERESA D

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 07/17/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/919,635

Applicant(s)

NOLAN ET AL.

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-37 and 39-45 is/are pending in the application.
- 4a) Of the above claim(s) 39-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Status of Claims

Claims 26-37 and 39-45 are pending in the application.

Claims 1-22 have been canceled in the Preliminary Amendment of 7/31/01. Claims 23-50 have been added in said Preliminary Amendment.

Claims 23-25 and 46-50 have been cancelled in the Amendment of 12/26/02. Claim 38 has been cancelled in the 5/13/03 Amendment.

Claims 39-45 are withdrawn from consideration as being drawn to non-elected species.

Claims 26-37 are under examination.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26-37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the

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time the application was filed, had possession of the claimed invention for reasons advanced in the last Office action.

Response to Arguments

Applicants argue that one skilled in the art would understand that the target molecule is not a part of the randomized nucleic acid, but is the molecule with which the bioactive agent interacts. In response, the claims do not recite for a method by which the target molecule, which is not a part of the randomized nucleic acid, binds with said random nucleic acid. Rather, the claim simply recites that the random nucleic acid is contacted with a cell that affects the cell phenotype. It is not readily apparent from the process steps whether the target molecule is in the cell and contacted with the nucleic acid or the expressed nucleic acid is contacted with the target.

Applicants argue that the claims have been amended to clarify the nature of the presentation structure, which is a polypeptide structure encoded by the nucleic acid sequences. Page 6, lines 20-34 is alleged to provide a detailed description of such structures, which are sequences that when fused to candidate bioactive agents, causes the candidate agents to assume a conformationally restricted form. In reply, the cited section merely provides a functional description of the

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presentation structure and definition of a polypeptide encoded by the nucleic acid sequences. It does not recite the kind or manner by which fusion to the bioactive agent results in the agent assuming a conformationally restricted form. Neither is there a description as to what constitutes a conformationally restricted form. Thus, the specification does not describe a structure for said presentation sequence. It is not apparent from the description as to the sequence that fuses to the bioactive peptide for the peptide to assume a conformationally restricted form, consequently, have a biological effect.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons set forth in the last Office action.

Response to Arguments

A). Applicants argue that the amendment to claim 26 obviates the rejection. In reply, the amendment partly overcomes the rejection. It is partly maintained with respect to the rejection that the metes and bounds of the "different nucleotide sequence"; a "plurality" of cells and "randomized candidate n.a."; "plurality of randomized peptides" and "phenotype of a cell" are not clearly set forth, especially in the absence of positive support in the specification. [See further the rejection below as applied to the newly amended claims).

B). It is argued that claim 27 has been amended to recite the identification of the target. In response, the newly amended claim simply recite the language "to identify said target". But does not establish a nexus between the isolating steps and identifying step. Mere isolation of e.g., a cell does not necessarily mean the phenotype of a cell has been identified.

C). Applicants argue that claim 28 properly limits the base claim. Claim 26 recites for identification of a target and claim 28 further specifies that the target is isolated. In response, there is nothing in the base claim 26 either in the preamble or body of the claim that recites for an isolating step. Except, of

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course, for claim 28, reciting that it is isolated. (See further below as applied to this newly amended claim).

D). Applicants argue that claim 29 has been amended for clarity. In reply, see rejection below for this amended claim.

E). Moot in view of the cancellation of claim 38.

The newly amended claims are rejected under this statute as follows:

1. Claim 26 is unclear for omitting essential step. The omitted step is the method by which the target molecule is identified. The body of the claim recites that the randomized library of nucleic acid is introduced into a cell. It is unclear whether upon contact with the cell, the nucleic acid binds with the target or the nucleic acid is expressed by the cell then contacted with the target molecule. The preamble appears to recite that the transdominant bioactive peptide is in the cell. The claim is so confusing as to what is actually or intended to be claimed.

2. Claim 28 is unclear as to the step of isolating a target molecule using said nucleic acid sequences or said randomized bioactive peptides. This limitation is already recited in the base claim. A nucleic acid sequences is not

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different from the randomized peptides encoded by said nucleic acid sequences.

3. Claim 29 broadens and/or at odds with the base claim.

The base claim does not recite that the nucleic acids encodes a presentation structure i.e., an additional component besides the random peptides.

Double Patenting

Claims 26-38 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-13 of prior U.S. Patent No. 6,153,380 ('380 Patent) or claims 26 and 29-36 of the instant invention over claims 1 and 8- 15 of the published application 2002/0146710 ('710 published application) for reasons of record.

In view of the amendments to the claims, the 101 double patenting rejection over the '380 Patent no longer applies. However, the rejection under the '710 published application is maintained.

Response to Arguments

Applicants argue that the provisional rejection over the '710 published application is properly addressed by allowance of one application, in the absence of other outstanding rejections, at which time a determination of double patenting can be made based on the issued claims. In reply, 37 CFR 1.78(b) provides

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that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 26-28 and 30-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Jensen et al (2001/0053523) for reasons advanced in the last Office action.

Response to Arguments

Applicants admit that Jensen can be available as a reference as of the PCT filing date of May 31, 1996. The present application is argued to claim priority to USSN 08/589,911 filed on 1/23/1996. Therefore, the Jensen reference is argued not to be a prior art. In response, USSN 08/589,911 however, has a different inventive entity from the present application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 23-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen in view of either Luzzago (Gene) or Dower et al (WO 91/19818) for reasons advanced in the last Office action.

Response to Arguments

The response above with respect to Jensen is applied herein since applicants presented the same argument over the Jensen

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reference. Applicants admit that Luzzago describes a library of peptides inserted into the n-terminal region of a bacteriophage coat protein, with two cysteine residues flanking the insert. But argue that the library of Luzzago was not screened for an intracellular effect but was selected for binding to antibodies. In response, applicants are attacking the references individually when the rejection is based on combination of references. Luzzago is employed for the purpose of the conventionality of a method wherein a library contains a presentation sequence. Applicants apply the same argument to the Dower reference. In reply, the same response for Luzzago is applied for Dower.

No claim is allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action

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is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


This application contains claims 39-45 drawn to an invention nonelected with traverse in Paper No. 10. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


T. D. Wessendorf
Primary Examiner
Art Unit 1627

tdw

7/16/03